CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75256_S7

CORRESPONDENCE

75256 6.1

ANDAs (See Attachment)

JAN 11 2002

Duramed Pharmaceuticals, Inc.
A Subsidiary of Barr Laboratories, Inc.
Attention: John Raposa
5040 Lester Road
Cincinnati, OH 45213

Dear Madam:

We acknowledge receipt of your communication dated October 26, 2001, submitted as required by the provisions of Regulation 21 CFR 314.72(a) and Section 505(k) of the Federal Food, Drug and Cosmetic Act for the drug products listed in the attachment.

Your letter details the transfer of ownership of the ANDAs from Duramed Pharmaceuticals Inc. to Duramed Pharmaceuticals, Inc. a Subsidiary of Barr Laboratories, Inc. We understand that Duramed Pharmaceuticals, Inc. is a separate legal entity that has assumed responsibility of the products listed in the attachment.

Pursuant to 21 CFR 314.72(b), the new owner shall advise FDA about any change in the conditions of the approved applications.

The material submitted is being retained as part of your applications.

Sincerely yours,

/S/

William P. Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachment

ANDAs:	Drug Products
40-207	Prochlorperazine Maleate Tablets USP, 5 mg and 10 mg
40-212	Estradiol Tablets USP, 0.5 mg, 1 mg, 1.5 mg and 2 mg
40-223	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg, 300 mg/30 mg and 300 mg/60 mg
40-233	Methotrexate Tablets USP, 2.5 mg
40-272	Oxycodone and Acetaminophen Tablets USP, 5 mg/325 mg
40-289	Oxycodone and Acetaminophen Tablets USP, 5 mg/500 mg
40-296	Estropipate Tablets USP, 0.75 mg, 1.5 mg and 3 mg
40-311	Medroxyprogesterone Acetate Tablets USP, 2.5 mg, 5 mg and 10 mg
40-318	Meperidine Hydrochloride Tablets USP, 50 mg and 100 mg
74-477	Captopril Tablets USP, 12.5 mg, 25 mg, 50 mg, 100 mg
74-550	Glipizide Tablets USP, 5 mg and 10 mg
74-991	Loperamide Hydrochloride Solution, 1 mg/5 mL
75-020	Hydroxyurea Capsules USP, 250 mg and 500 mg
75-052	Triamterene and Hydrochlorothiazide Capsules USP, 37.5 mg/25 mg
75-072	Verapamil Hydrochloride ER Tablets USP, 120 mg and 240 mg
75-110	Cimetidine Hydrochloride Oral Solution, 300 mg/5 mL
75-256	Apri® (Desogestrel and Ethinyl Estradiol) Tablets, 0.15 mg/0.03 mg
75-796	Aviane™ (Levonorgestrel and Ethinyl Estradiol) Tablets USP, 0.1 mg/0.02 mg
75-809	Empresse™ (Levonorgestrel and Ethinyl Estradiol) Tablets USP, 0.05 mg/0.03 mg, 0.075 mg/0.04 mg and 0.125 mg/0.03 mg
88-119	Isoniazid Tablets USP, 300 mg
88-231	Isoniazid Tablets USP, 100 mg
88-497	Methylprednisolone Tablets USP, 4 mg

CER submitted 4/5/02

Barr Laboratories, Inc.

5040 Duramed Drive, Cincinnati, OH 45213 • 513/731-9900

SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED IN 30 DAYS

March 28, 2002

RECEIVED
MAR 2 9 2002
OGD / CDER

Office of Generic Drugs, CDER
FOOD AND DRUG ADMINISTRATION
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

RE: ANDA 75-256 Apri® (Desogestrel and Ethinyl Estradiol) Tablets, 0.15 mg/0.03 mg

SUBJECT: Alternate Analytical Testing Laboratory

Reference is made to our approved Abbreviated New Drug Application submitted under Section 505(j) of the Federal Food, Drug and Cosmetic Act for Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg.

This submission provides for a Special Supplement-Changes Being Effected 30 Days for alternate analytical testing laboratories for Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg. The alternate analytical testing laboratories are located at:

Barr Laboratories, Inc.	Barr Laboratories, Inc.
2150 Perrowville Road	2 Quaker Road, Bldg. # 1
Forest, Virginia 24551	Pomona, New York 10970

In accordance with the Guidance for Industry - Changes to an Approved NDA or ANDA issued November 1999, Section VI. 1.C., Duramed Pharmaceuticals Inc., a subsidiary of Barr Laboratories, Inc. is submitting the 2150 Perrowville Road site ("VA") and the 2 Quaker Road site ("NY") as alternate analytical testing laboratories based on the following:

1. The test methods approved in the affected applications and methods that have been implemented under 21 CFR 314.70(d) are being used at the VA and NY sites.
2. All post approval commitments relating to the test methods have been fulfilled.
3. The VA and NY testing facilities have the capability to perform the intended testing. Information to support the capability of the VA and NY laboratories will be available for FDA investigator review.

4. The VA and NY testing facilities have had a satisfactory current good manufacturing practice (cGMP) inspection within the last 2 years. During the period of August 20 through the 24 and the 27 through the 30, 2001, the Baltimore District inspected the Virginia site and found it to comply with cGMPs. The NY site was inspected on June 20 through 22 and the 25 through the 29, 2001 by the New York District and found it to comply with cGMPs.

Barr's alternate testing laboratories located at the Virginia facility and New York facility are both full service analytical laboratories capable of performing microbiological and chemical testing on: (1) raw materials, i.e., drug substances and inactive ingredients, (2) in-process samples, and (3) finished product samples, i.e., release, validation and stability. These alternate laboratories will test all samples by the approved analytical methods and/or the current official compendial or regulatory methods.

Attached please find the following documentation to support this Special Supplement-Changes Being Effected 30 Days:

- cGMP Certification Statement for the VA and NY analytical testing laboratories.

The implementation date for this Special Supplement-Changes Being Effected 30 Days is April 28, 2002.

This supplement consists of two (2) copies, an archival copy and a review copy. We certify that a true copy of the supplement as described in 21 CFR 314.71 (b) has been provided to the Food and Drug Administration, Baltimore District Office, New Jersey District Office, Cincinnati District Office and New York District Office. A document certification is attached.

Sincerely,

DURAMED PHARMACEUTICALS INC.,
a subsidiary of BARR LABORATORIES, INC.

Annette Arlington /for
Christine Mundkur
Sr. Vice President, Quality and Regulatory Counsel

DURAmed

The Art of Leadership...
The Science of Change

Duramed Pharmaceuticals, Inc.
5040 Duramed Drive
Cincinnati, Ohio 45213

(513) 731-9900
(800) 543-8338

October 26, 2001

Office of Generic Drugs, CDER
FOOD AND DRUG ADMINISTRATION
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

NC

REFERENCE: ANDA No. 75-256 Apri® (Desogestrel and Ethinyl Estradiol) Tablets, 0.15 mg/0.03 mg

Subject: Transfer of Ownership

Reference is made to Duramed's Approved Abbreviated New Drug Application ("ANDA") submitted under Section 505(j) of the Federal Food, Drug and Cosmetic Act for Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg.

Duramed Pharmaceuticals Inc. was recently purchased by Barr Laboratories Inc. and in accordance with 21 CFR §314.72(a)(1), Duramed Pharmaceuticals, Inc. has transferred all rights, title and interest of Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg ANDA No. 75-256, to the following company:

Duramed Pharmaceuticals, Inc.
5040 Lester Road
Cincinnati, Ohio 45213
A subsidiary of Barr Laboratories Inc.

The products will continue to be manufactured by Duramed Pharmaceuticals Inc., which reports directly into Barr Laboratories, Inc. Barr Laboratories, Inc. and its subsidiary Duramed Pharmaceuticals Inc. will be responsible for all GMP, regulatory, manufacturing, packaging, sales, and distribution responsibilities. Labeling changes will be submitted in the next Annual Report.

Duramed Pharmaceuticals Inc. has a complete copy of the application, amendments, annual reports and correspondences related thereto. Enclosed please find a copy of Duramed Pharmaceuticals Inc., a subsidiary of Barr Laboratories Inc., acceptance of ownership letter, dated October 26, 2001, on page 5.

An identical copy of this letter has been provided to the New York and Cincinnati District Offices. A document certification is attached.

This completes the present transfer of ownership effective on October 26, 2001. If you have any questions, please contact me by phone at (513) 731-9900 or by fax at (513) 731-5270.

Sincerely,

DURAMED PHARMACEUTICALS, INC.

John R. Rapoza, M.S., R.Ph.
Sr. Vice President, Regulatory Affairs

cc: New York, and Cincinnati District Field Offices